REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1, 3-4, 11-28, 41 and new Claims 62-63, the only claims pending and under examination.

FORMAL MATTERS

Claims 1-28 and 41 have been examined and rejected.

Claims 29-40, and 42-61 have been previously withdrawn.

Claim 1 has been amended to add the limitations of Claim 8. Support for this amendment can be found in canceled Claim 8, as well as in the specification, for example p. 10, lines 14-15 [paragraph 0035].

Claims 3, 4 and 20 have been amended to correct their dependency. Support for these changes can be found for example in the specification on page 12, lines 14-18, page 13, lines 5-9 [paragraph 0040], and page 53 line 31-page 54, lines 1-7.

Claims 2, and 5-10 have been canceled.

New Claims 62-63 have been added. Support for these claims can be found in the specification for example on p. 15, lines 2-3 [paragraph 0044]; p. 53, lines 7-29 [paragraph 00137], and on p. 54, lines 13-21 [paragraph 00139]. Accordingly, no new matter has been added.

As no new matter has been added by the above amendments, entry thereof by the Examiner is respectfully requested.

Double Patenting Rejection

Claims 1, 11, 12, and 27 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 30 of USPN 7,149,574.

Solely in order to expedite prosecution, and in no way agreeing with the Examiner's assertions, a Terminal Disclaimer under 37 CFR 1.321 is herewith submitted to overcome this rejection.

Accordingly, the Applicants respectfully request that the nonstatutory obviousness-type double-patenting rejection of Claims 1, 11, 12, and 27 be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 1-7, 9,10,14,16,19-22, 28, and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gambardella et al. (Metabolism, 46, 3, March 1999, p. 291-297). Independent Claim 1 has been amended to incorporate the limitations of Claim 8. As Claim 8 was free of the rejection under 35 U.S.C. § 102(b), the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1-7, 9,10,14,16,19-22, 28, and 41 be withdrawn.

Claims 1-7, 9, 10, 21, 28, and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Brevetti et al. (Brief communications, Nov. 1981, p 938-941). Independent Claim 1 has been amended to incorporate the limitations of Claim 8. As Claim 8 was free of the rejection under 35 U.S.C. § 102(b), the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1-7, 9, 10, 21, 28, and 41 be withdrawn. As Claims 2, 5-7 and 9-10 have been canceled, rejections of those claims are moot.

Claims 1, 21 and 41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nordling et al. (E Urol, 1992, 21, 328-331). Independent Claim 1 has been amended to incorporate the limitations of Claim 8. As Claim 8 was free of the rejection under 35 U.S.C. § 102(b), the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1, 21, and 41 be withdrawn.

Claims 1-7, 9,10-12, 15, 17, 21, and 22 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Majcherczyk et al. (Br J Pharmacol, 1987, 91(4), 711-4). Independent Claim 1 has been amended to incorporate the limitations of Claim 8. As Claim 8 was free of the rejection under 35 U.S.C. § 102(b), the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1-7, 9, 10-12, 15, 17,

21, and 22 be withdrawn. As Claims 2, 5-7 and 9-10 have been canceled, rejections of those claims are moot.

Claims 1, 21, 23-25, and 28 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Davies, et al. (The J of Intl Med Research, 1988, 16, 173-181). Independent Claim 1 has been amended to incorporate the limitations of Claim 8. As Claim 8 was free of the rejection under 35 U.S.C. § 102(b), the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1, 21, 23-25, and 28 be withdrawn.

Claims 1 and 26-27 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Hill, et al. (U.S. Patent 6,449,507). Independent Claim 1 has been amended to incorporate the limitations of Claim 8. As Claim 8 was free of the rejection under 35 U.S.C. § 102(b), the Applicants respectfully request that the 35 U.S.C. § 102(b) rejection of Claims 1 and 26-27 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 8, 13, and 18 have been rejected under 35 U.S.C. § 103(a) as being obvious over Gambardella et al. (Metabolism, 46, 3, March 1999, p. 291-297).

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. *See Pharmastem Therapeutics v. Viacell et al.*, 2007 U.S. App. LEXIS 16245 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (*citing KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007))); *and see Omegaflex, Inc. v. Parker-Hannifin Corp.*, 2007 U.S. App. LEXIS 14308 (Fed. Cir. 2007) ("[t]he Supreme Court recently explained that 'a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art,'" (*citing KSR Int'l Co.* at 1741)); *and see Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006) ("[once] all claim limitations are found in a number of prior art references, the factfinder must determine '[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references,'" (*citing In re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004))).

Gambardella, et al. teach a method of treating an autonomic nervous system dysfunction, mainly due to deficient parasympathetic activity, that is associated with an elevated basal metabolic rate in cancer patients. As the Examiner states, "[Gambardella] does not teach a method of treating conditions caused by abnormality in autonomic nervous system wherein the abnormality is characterized by normal sympathetic activity or substantially equal parasympathetic and sympathetic functions in at least a portion of said autonomic nervous system." The Examiner continues that it would have been obvious to one of ordinary skill in the art at the time of the invention to administer a beta blocker such as propranolol in treating a condition caused by an abnormality in autonomic nervous system where the abnormality is characterized by normal sympathetic activity [Office Action, p. 7-8].

The Applicants respectfully disagree. Claims 13 and 18 ultimately depend from amended Claim 1 which now incorporates the limits of Claim 8.

Gambardella fails to teach or suggest the element of treating a condition wherein modulating of the autonomic nervous system results in substantially equal parasympathetic and sympathetic functions in at least a portion of the autonomic nervous system. Gambardella fails to teach or suggest this element because the method in Gambardella involves the use of propranolol to block the effects of the sympathetic nervous system. Nowhere in Gambardella does it disclose treating a condition wherein modulating of the autonomic nervous system results in substantially equal parasympathetic and sympathetic functions in at least a portion of the autonomic nervous system.

Therefore, a prima facie case of obviousness has not been established because Gambardella fails to teach or suggest all the elements of the rejected claims. Consequently, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 13 and 18 be withdrawn.

New claims 62 and 63 are patentable for at least the reasons provided above.

CONCLUSION

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PALO-002.

Respectfully submitted,
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